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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,160

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Curt Horvath

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CROWELL & MORING LLP  
INTELLECTUAL PROPERTY GROUP  
P.O. BOX 14300  
WASHINGTON, DC 20044-4300

EXAMINER

ANGELL, JON E

ART UNIT

PAPER NUMBER

1635

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,160	<b>Applicant(s)</b> HORVATH ET AL.	
	<b>Examiner</b> J. E. Angell	<b>Art Unit</b> 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

Claims 1-47 are currently pending.

#### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 9-15 drawn to a method of mediating stat3 signaling in a cell by administering to the cell a polypeptide having at least 80% identity with SEQ ID NO: 1 (Mumps V protein).

Group II, claim(s) 5-8, drawn to a method of mediating stat3 signaling in a cell by administering to the cell a nucleic acid sequence having a sequence at least 80% identical to SEQ ID NO: 2 (a sequence encoding Mumps V).

Group III, claim(s) 16-19, 24-29 drawn to a method for inhibiting the growth of a tumor by administering to the tumor a polypeptide having at least 80% identity with SEQ ID NO: 1 (Mumps V protein).

Group IV, claim(s) 20-23, drawn to a method for inhibiting the growth of a tumor by administering to the tumor a nucleic acid sequence having at least 80% identity with SEQ ID NO: 2.

Group V, claim(s) 30-33, 36-38 drawn to a method for inhibiting an inflammatory reaction by administering to a subject a polypeptide having at least 80% identity with SEQ ID NO: 1 (Mumps V protein).

Group VI, claim(s) 34, 35, drawn to a method for inhibiting an inflammatory reaction by administering to a subject a nucleic acid sequence having at least 80% identity with SEQ ID NO: 2.

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Group VII, claim(s) 39-42, 45-47 drawn to a method for an autoimmune disease by administering to a subject a polypeptide having at least 80% identity with SEQ ID NO: 1 (Mumps V protein).

Group VIII, claim(s) 43, 44 drawn to a method for inhibiting an autoimmune disease by administering to a subject a nucleic acid sequence having at least 80% identity with SEQ ID NO: 2.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the groups of inventions are not linked by a special technical feature. PCT. PCT Rule 13.2 states “The expression ‘special technical features’ shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes *over the prior art*”(Emphasis added). In the instant case, however, there is a lack of unity since the broadest claim does not provide a special technical feature over the prior art (Nemunaitis, Investigational New Drugs, 1999; Vol. 17, pages 375-386). Instant claim 1 encompasses a method comprising contacting a cell with a STAT inhibitor and claim 5 further limits claim 1 by indicating that the inhibitor a protein expressed from a nucleic acid at least 80% identical to SEQ ID NO: 1 (Mumps V gene). Therefore, the claims encompass a method comprising contacting a cell with a nucleic acid which expresses a protein encoded by SEQ ID NO: 1 (Mumps V). Nemunaitis teaches contacting a cell with a mumps virus. It is noted that the mumps virus is a nucleic acid molecule comprising SEQ ID NO: 1 (Mumps V gene) and would express the Mumps V protein and expression of the Mumps V protein in the cell would necessarily result decrease of STAT 3 even if Nemunaitis did not recognize it (see page 377, under “Mumps Virus”). Accordingly, there is no special technical feature over the prior art.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

2. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of contacting are as follows:

- 1) contacting cells in vitro
- 2) contacting cells in vivo

Applicant is required, in reply to this action, to elect a single species of contacting to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently

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added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The species of cytokines are as follows:

- 1) growth hormone
- 2) IL8
- 3) IL10
- 4) G-CSF

Applicant is required, in reply to this action, to elect a single species of cytokine to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The species of inflammatory reactions are as follows:

- 1) Crohn's disease
- 2) inflammatory bowel disease
- 3) multiple sclerosis
- 4) ischemia
- 5) stroke
- 6) traumatic brain injury
- 7) spinal injury
- 8) rheumatoid arthritis
- 9) atherosclerosis

Applicant is required, in reply to this action, to elect a single species of inflammatory reactions to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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The species of autoimmune diseases are contacted are as follows:

- 1) insulin dependent diabetes mellitus
- 2) systemic lupus erythremetosis
- 3) psoriasis

Applicant is required, in reply to this action, to elect a single species of autoimmune disease to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

3. The claims are deemed to correspond to the species listed above in the following manner:

Claim(s) 1-29 are generic to the species of contacting.

Claim(s) 1-15 are generic to the species of cytokines.

Claim(s) 30-38 are generic to the species of inflammatory reactions.

Claim(s) 39-47 are generic to the species of autoimmune diseases.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species were well known to those of skill in the art, thus there is no special technical feature linking the species.

**Applicant is advised that the reply to this requirement to be complete must include**

**(i) an election of a species to be examined** even though the requirement may be traversed (37

CFR 1.143) and (ii) **identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m. .



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/  
Primary Examiner, Art Unit 1635